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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/735,318	12/12/2003	Charles E. Lundy	OT01455	2216

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SCHERING-PLOUGH CORPORATION
PATENT DEPARTMENT (K-6-1, 1990)
2000 GALLOPING HILL ROAD
KENILWORTH, NJ 07033-0530

EXAMINER	
SHEIKH, HUMERA N	
ART UNIT	**PAPER NUMBER**
1615	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/735,318	LUNDY ET AL.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/6/04; 5/2/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Receipt of the Information Disclosure Statements (IDS) filed 02/06/04 and 05/02/06 is acknowledged.

Claims 1-12 are pending in this action. Claims 1-12 are rejected.

Inventorship

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Specification

The disclosure is objected to because of the following informalities:

In the specification, on page 5, line 15, sealing surface "14" should instead read as "sealing surface 14A".

Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-7 and 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ebert et al. (WO 96/19205) in view of Chiang et al. (U.S. Pat. No. 4,973,468) and further in view of Min *et al.* (U.S. Pat. No. 5,916,587).

Ebert *et al.* ('205) teach a transdermal delivery device for administering an active agent to the skin or mucosa of an individual comprising a laminated composite of an adhesive overlay (26), a backing layer (14) underlying the central portion of the adhesive overlay, an active agent-permeable membrane (16), the backing layer and membrane defining a reservoir (12) that contains a formulation of the active agent, a peel seal disc (20) underling the active agent-permeable membrane, a heat seal (22) about the periphery of the peel seal disc the active agent-permeable membrane and the backing layer and a removable release liner (24) underlying the

exposed overlay and peel seal disc. The adhesive layer is above and peripheral to the path of the active agent to the skin or mucosa and is protected from degradation by the components of the reservoir by a multiplicity of heat seals. The peel seal disc protects against release of the active agent-containing reservoir and the release liner protects the adhesive from exposure to the environment prior to use (see Abstract) and (page 3, line 24 – pg. 4, line 10).

The formulation contained in the reservoir may include *solvents*, gelling agents, stabilizers, antiirritants and other additives (p. 8, lines 11-22).

Ebert *et al.* teach a membrane layer, which may or may not be a rate-controlling element depending upon the particular drug involved, the permeability of the skin to the drug, and the rate of delivery required to provide therapy (p. 8, line 23 – p. 9, line 2). Ebert *et al.* teach the inclusion of microporous membranes, which is equivalent to Applicant's claimed limitation of 'at least one opening in the cover for said reservoir'. (p. 9, line 3-7).

Ebert *et al.* also teach fatty acid esters, such as glyceryl monoleate (Example 1- p. 11, line 6).

Ebert *et al.* do not teach a polymeric thickening agent and a dialkylene glycol alkyl ether, such as dialkylene glycol monoethyl ether.

Chiang *et al.* ('468) teach skin permeation enhancer compositions, which increase the permeability of skin to transdermally administered pharmacologically active agents. The composition contains diethylene glycol monoethyl ether in addition to an ester component such as propylene glycol monolaurate, methyl laurate or the like (see Abstract); (col. 3, lines 8-18; 54-

64); (col. 5, line 65- col. 6, line 6). The ether component aids in increasing the skin flux of a selected drug and may act as a solubilizer or vehicle (col. 6, lines 7-17).

The drug/permeation enhancer reservoir may comprise polymeric materials, such as hydrophobic polymers that may serve as thickening agents (col. 6, line 61 – col. 7, line 3).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate polymeric thickening agents and a dialkylene glycol alkyl ether, such as diethylene glycol monoethyl ether, as taught by Chiang *et al.* within the transdermal device of Ebert *et al.* One of ordinary skill in the art would be motivated to do so with a reasonable expectation of success because Chiang *et al.* teach polymeric thickening agents used for their thickening properties and also teach a dialkylene glycol alkyl ether (*i.e.*, diethylene glycol monoethyl ether) that functions to aid in increasing the skin flux of a drug and acts as a solubilizer or vehicle. The expected result would be an enhanced transdermal delivery system for the effective delivery of active agents.

* * * * *

The teachings of Ebert *et al.* are delineated above. Ebert *et al.* do not teach an alkylene glycol, such as propylene glycol.

Min *et al.* ('587) teach a transdermal delivery system comprising solvents, used as an absorption assistant that dissolves active substances, whereby suitable solvents disclosed include propylene glycol (see col. 2, line 66 – col. 3, line 2). Additional solvents disclosed include diethylene glycol monoethyl ether (col. 3, line 4).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate solvents, such as an alkylene glycol, particularly, propylene glycol as taught by Min *et al.* within the transdermal device of Ebert *et al.* One of ordinary skill in the art would be motivated to do so with a reasonable expectation of success because Min *et al.* teach a transdermal delivery system comprising solvents, (i.e., propylene glycol; diethylene glycol monoethyl ether), whereby the solvent (propylene glycol) functions in dissolution of active substances. The expected result would be an improved transdermal delivery system that exhibits enhanced dissolution of active substances.

* * * * *

Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ebert *et al.* (WO 96/19205) as applied to claims 1-7 and 10-12 above and further in view of Toppo (U.S. Pat. No. 5,985,860).

The teachings of Ebert *et al.* are discussed above. Ebert *et al.* do not teach an active agent being salicylic acid.

Toppo ('860) teaches a transdermal delivery system comprising pain-relieving substances (see Abstract). Suitable and effective pain relieving medicaments disclosed include salicylic acid (see column 3, lines 29-35) and Claim 9.

Example twenty (20) at column 8, lines 31-51 demonstrates preparation of a transdermal solution containing 6% by weight of salicylic acid. ((This amount reads on Applicant's claimed range of from about 5% to about 40% by weight of salicylic acid (claim 9)).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate active agents, such as salicylic acid as taught by Toppo within the transdermal device of Ebert *et al.* One of ordinary skill in the art would be motivated to do so with a reasonable expectation of success because Toppo teaches a transdermal delivery system comprising pain-relieving medicaments, such as salicylic acid and teach that such medicaments are suitable active agents for effectively reducing pain in an individual. The expected result would be an improved transdermal drug delivery system, used for the alleviation of pain.

* * * * *

Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ebert *et al.* (WO 96/19205) as applied to claims 1-7 and 10-12 above and further in view of Franke *et al.* (WO 01/26637).

The teachings of Ebert *et al.* are discussed above. Ebert *et al.* do not teach an active agent being salicylic acid.

Franke *et al.* ('637) teach a transdermal therapeutic system for administering salicylic acid and/or acetylsalicylic acid. The system has a backing layer, an active ingredient reservoir attached thereto, a membrane which controls the administration of the active ingredient in the absence of other control mechanisms, an adhesive device for fixing the system onto the skin and a protective layer which can be detached before application (see Abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate active agents, such as salicylic acid as taught by Franke *et al.* within the transdermal device of Ebert *et al.* One of ordinary skill in the art would be motivated to do so with a reasonable expectation of success because Franke *et al.* teach pain-relieving medicaments, such as salicylic acid, administered through a transdermal therapeutic system to alleviate pain. The expected result would be a highly effective transdermal therapeutic system, used to deliver medicaments, particularly for the reduction of pain to a subject in need thereof.

While the amounts of salicylic acid are not disclosed in the '637 Abstract, it is the position of the Examiner that suitable amounts could be determined by one of ordinary skill in the art through the use of routine or manipulative experimentation to obtain optimal results, as these are indeed variable parameters attainable within the art. Moreover, the Examiner points out that generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller,* 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). In this instance, the prior art expressly teaches administration of the same active agent - saclicylic acid, employed for the same purpose (i.e., treat pain) and used for the same field of endeavor (transdermal delivery) as that desired by Applicants. Thus, no unexpected results have been observed, which accrue from the instant salicylic acid amounts claimed.

Pertinent Art

Prior Art, made of record and cited of interest by the Examiner:

- **Carrara** (USPN 6,231,885) (05/2001):

  Carrara teaches a patch for transdermal administration of drugs consisting essentially of: a) a flexible backing layer; b) an adhesive layer comprising a pressure-sensitive adhesive matrix, a cohesion improver, a tackifier agent and a combination of permeation enhancers and c) a protective liner that is removed prior to use (see Abstract).

Conclusion

--No claims are allowed at this time.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday during regular business hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

HUMERA N. SHEIKH
PRIMARY EXAMINER
Art Unit 1615

March 31, 2007

hns